

REMARKS

Claims 2 and 5 have been cancelled.

Claim 1 has been amended to recite "[a] recombinant microorganism belonging to the genus *Escherichia* and being capable of producing vitamin B6, wherein said microorganism carries extra nucleic acids encoding an enzyme combination selected from:

- i) erythrose 4-phosphate dehydrogenase and 1-deoxy-D-xylulose 5-phosphate synthase;
- ii) erythrose 4-phosphate dehydrogenase and pyridoxol 5'-phosphate synthase; and
- iii) erythrose 4-phosphate dehydrogenase, 1-deoxy-D-xylulose 5-phosphate synthase and pyridoxol 5'-phosphate synthase."

Support for this amendment is found in the specification at, for example, page 1, lines 10-24; in Examples 1-12; and in original claims 2 and 5. See *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l) (8th ed. Rev. 5, August 2006, pp. 600-92 and 600-84).

Claim 4 has been amended to recite "[a] process for preparing vitamin B6 comprising the steps of:

- i) culturing a recombinant microorganism belonging to the genus *Escherichia* and carrying extra nucleic acids encoding erythrose 4-phosphate dehydrogenase in expressible form, in a fermentation broth; and

ii) separating the resulting vitamin B6 from the fermentation broth.”

Support for this amendment is found in the specification at, for example, page 1, lines 10-24; in Examples 1-12; and in original claims 2 and 5. (*Id.*).

Claim 8 has been amended to depend from claim 4.

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

Objections to the Specification:

The Examiner objected to the disclosure by asserting that “in the specification there is no statement that indicates that the instant application is the US National Stage filing of PCT Application No. PCT/EP03/10403, filed 09/18/2003” (Paper No. 20070131 at 2). The Examiner further asserted that “[t]his should appear as the first sentence of the specification following the title,” (*Id.*).

It is respectfully submitted that the Examiner is mistaken. We note that a PRELIMINARY AMENDMENT was filed on March 23, 2005, which amended the specification to recite:

This application is the National Stage of International
Application No. PCT/EP2003/010403, filed September 18,
2003.

(See Exhibit 1: Preliminary Amendment filed March 23, 2005 and Date Stamped Postcard of March 23, 2005). In view of the Preliminary Amendment, it is respectfully submitted that the Examiner’s objection to the specification is moot and should be withdrawn.

The Examiner also objected to the disclosure by asserting that “a paper copy of the Sequence Listing has not been received.” (*Id.*).

It is respectfully submitted that the Examiner is again mistaken. In response, we note that a STATEMENT UNDER 37 C.F.R. §1.821 together with an electronic and paper copy of the Sequence Listing were filed on March 23, 2005. A copy of these papers along with a date stamped postcard evidencing receipt of same by the PTO is attached as Exhibit 2. As is well settled, "[a] postcard receipt which itemizes and properly identifies the items which are being filed serves as *prima facie* evidence of receipt in the USPTO of all the items listed thereon on the date stamped thereon by the USPTO." See MPEP § 503. In view of the foregoing, it is respectfully submitted that the Examiner's objection to the specification is moot and should be withdrawn.

§112, First Paragraph Rejections:

1. Written Description

Claims 1-8 have been rejected under 35 U.S.C. §112, first paragraph. (Paper No. 20070131 at 4). In making the rejection, the Examiner asserted that "[t]he claims are drawn to a genus of recombinant microorganisms comprising a genus of erythrose 4-phosphate dehydrogenases, a genus of 1-deoxy-D-xylulose-5-phosphate synthases, and a genus of pyridoxol 5' -phosphate synthases for which no structure and amino acid or nucleotide sequence is apparent," and "the claims encompass any genes encoding any erythrose 4-phosphate dehydrogenase, any genus of 1-deoxy-D-xylulose-5-phosphate synthases, and any pyridoxol 5'-phosphate synthases." (*Id.* at 4-5). The Examiner then concluded that "applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of any genes encoding any erythrose 4-

phosphate dehydrogenase, any genus of 1-deoxy-D-xylulose-5-phosphate synthases, and any pyridoxol 5'-phosphate synthases." (*Id.* at 5).

With a view towards furthering prosecution, claim 1 has been amended to recite that the recombinant microorganism belongs "to the genus *Escherichia*" and that the "microorganism carries extra nucleic acids" encoding the three recited combinations.

Claim 4 has also been amended to recite that the recombinant microorganism belongs "to the genus *Escherichia*" and carries "extra nucleic acids encoding erythrose 4-phosphate dehydrogenase in expressible form, in a fermentation broth."

As amended, claims 1 and 4 recite a ***specific group of recombinant microorganisms***, *i.e.*, a recombinant microorganism belonging to the genus *Escherichia*. In view of these amendments, the Examiner's concern regarding the breadth of the claims is rendered moot. Indeed, the rejection concedes that the specification discloses recombinant microorganisms belonging to the genus *E. coli*. (Paper No. 20070131 at 4).

Claims 1 and 4 have also been amended to replace the recitation of "genes" with "nucleic acids." In view of these amendments, the Examiner's concerns regarding gene structure are rendered moot. (Paper No. 20070131 at 5).

In view of the foregoing, it is respectfully submitted that the rejection has been rendered moot and should be withdrawn.

2. Enablement

Claims 1-8 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. (Paper No. 20070131 at 2). In making the rejection, the Examiner acknowledged that the specification is "enabling for (1) a recombinant *E.coli* host transformed with plasmids comprising a polynucleotide encoding erythrose 4-phosphate dehydrogenase obtained from *E.coli* chromosomal DNA ..., a polynucleotide encoding 1-deoxy-D-xylulose-5-phosphate synthase obtained from *E.coli* chromosomal DNA ..., and a polynucleotide encoding pyridoxol 5'-phosphate synthase obtained from *E.coli* chromosomal DNA ...," and (2) "a process for preparing vitamin B6 comprising culturing said recombinant *E.coli* host;" (*Id.*).

The Examiner, however, asserted that the claims were not commensurate in scope with the disclosure in the specification. (*Id.* at 2-3). In making this determination, the Examiner asserted "the claims encompass **any** recombinant microorganism capable of producing vitamin B6 which carries extra genes coding for **any** erythrose 4-phosphate dehydrogenase, **any** 1-deoxy-D-xylulose-5-phosphate synthase, and **any** pyridoxol 5' -phosphate synthase, where the genes and enzymes are from **any** biological source for which no structure and amino acid or nucleotide sequence is apparent, and **any** process for preparing vitamin B6 using said recombinant microorganism." (*Id.* at 3) (emphasis added).

With a view towards furthering prosecution, claims 1 and 4 have been amended as noted above. As amended, claims 1 and 4 recite a **specific group of recombinant microorganisms**, *i.e.*, a recombinant microorganism belonging to the genus *Escherichia*. With these amendments, it is respectfully submitted that the

Examiner's concerns regarding the scope of claims 1 and 4, *i.e.*, "**any** recombinant microorganism," "**any** biological source" for the enzymes, and "**any** process for preparing vitamin B6," is rendered moot. (Paper No. 20070131 at 3) (emphasis added).

As is well accepted, even a "considerable amount" of experimentation is permissible if it is merely routine or if the specification provides a reasonable amount of guidance. MPEP § 2164.05 and *In re Wands*, 8 USPQ at 1404. In addition, "a patent need not teach, and preferably omits, what is well known in the art." MPEP § 2164.01 (8th ed. Rev. 5, August 2006, p. 2100-187) *citing In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

In this regard, we note that the specification provides ample disclosure sufficient to inform a skilled artisan that the Applicants enabled the currently claimed recombinant microorganisms and processes for preparing vitamin B₆. For example, the specification discloses 12 examples that provide sufficient instruction to one skilled in the art on how to make and use the currently claimed **specific** group of recombinant microorganisms and how to use the currently claimed processes for preparing vitamin B₆ by culturing these recombinant microorganisms.

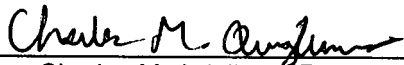
Indeed, the rejection recognizes that the specification provides guidance and working examples for recombinant *E.coli* microorganisms containing the recited nucleotide sequences. (Paper No. 20070131 at 3). It is respectfully submitted that identifying the recombinant microorganisms capable of producing vitamin B₆ according

to amended claims 1 and 4 is a matter of applying the disclosure in the specification of how to make such recombinant microorganisms and testing the vitamin B₆ productions of the recombinant microorganisms compared to *E. coli* AT1024. (See, e.g., Specification page 1, lines 10-24; page 4, line 19 - page 5, line 13; Examples 1-12; and Table 1). It is respectfully submitted that such activity is not undue experimentation.

For the reasons set forth above, it is respectfully submitted that the rejection has been rendered moot and should be withdrawn.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections and objections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on July 9, 2007.



Charles M. Avigliano, Reg. No. 52,578

Respectfully submitted,

By: Charles M. Avigliano
Charles M. Avigliano
Registration No. 52,578
BRYAN CAVE LLP
1290 Avenue of the Americas
New York, NY 10104-3300
Phone: (212) 541-2000
Fax: (212) 541-4630